

DETAILED ACTION

Claims 1-19 and 21-26 are pending in the application. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Response to Arguments

1. Applicant's arguments filed 11/2/09 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-19 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krone et al. (US 5,391,696) in view of Lewis (US 5,838,571) and in further view of Suzuki et al. (US 6,015,789) and Remington's Pharmaceutical Sciences **1990** 18th Ed. Chpt. 89. as stated in the office action mailed 7/30/09.

4. Applicant asserts that the references cannot render obvious amended claims 1,14,24 and 26, as neither references themselves nor the inferences and creative steps that a person of ordinary skill in the art would have employed at the time of the invention taught or suggested a polytartrate composition having "a lag phase of a predetermined time" in the release of a pharmaceutical composition as recited by amended claims

1,24,26, or actually "determining a time length of the lag phase" as recited by amended claim 14.

5. Krone et al. teaches polytartrate formulations which may comprise tablets formed via compaction/compression and do not comprise a barrier structure. Krone et al. teaches that polytartrate preparations have a decreased "initial burst" which implies that they have a second burst. In regards to the "lag time" the specification recites (p13, lines 17-20 and 30-33), "a secondary "lag phase" of *low or no* release of the drug followed by a second burst". Therefore, the polytartrate tablet formulations which are prepared via compaction/compression of Krone et al. encompass the composition of the instant claims as they have a first "initial burst", an implied second burst and the phase between the bursts (i.e. lag phase) which may release drug. Therefore, the time between bursts of the polytartrate formulations of Krone et al. encompass the "lag phase" of the instant claims.

6. Also, the recitation, "determining a time of the lag phase", is a mental step and does not contain any active technique (manual steps) for determining a time of the lag phase. There are no specific active steps to define how such determining is performed or which limit the amount of time of the lag phase.

Conclusion

7. No claims are allowed at this time.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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